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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,433	12/03/2003	Douglas J. Duchon	20144-500	5815

37374 7590 12/01/2005

INSKEEP INTELLECTUAL PROPERTY GROUP, INC  
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EXAMINER

LEWIS, KIM M

ART UNIT PAPER NUMBER

3743

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/726,433	DUCHON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20-35 is/are allowed.
- 6) ☒ Claim(s) 1, 3, 8-12, 14-17, 19, 36, 38, 43-45, 47-50, 52-54, 56-58, 60-62, 64, 65 and 67 is/are rejected.
- 7) ☒ Claim(s) 2, 4-7, 13, 18, 37, 39-42, 46, 51, 55, 59, 63 and 66 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

### DETAILED ACTION

**As indicated in the Notice of Withdrawl of Issue under 37 C.F. R 1.313, mailed July 21, 2005, prosecution of this application is reopened. Applicant should also note that this application has been transferred to Primary Examiner Kim M. Lewis, AU 3743.**

#### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1, 3, 9-12, 14-17, 19, 36, 38, 43-45, 47-50, 52-54, 56-58, 60-62, 64, 65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,802,425 ("Moulding, Jr.).

As regards claim 1, Moulding, Jr. substantially discloses applicant's presently claimed method of changing a gynecological condition of a female. Moulding, Jr

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discloses an intrauterine contraceptive device comprising: introducing an implant, which may contain a mesh material (col. 2, lines 29-30), into said uterus with a delivery tool (col. 4, lines 49-57); contacting said implant with uterine tissue so as to induce a tissue response in said uterus (constituted by engaging the fundus of the uterus), detaching said implant from said delivery tool: maintaining contact between said implant and said uterine tissue for at least so long that said tissue response causes a changed gynecological condition in said female (constituted by a period of infertility).

Moulding, Jr. fails to teach evaluating the condition of a uterus of said female and further fails to teach that the implant is a presterilized implant. The examiner, however, contends that both limitations are either inherent and/or would have been obvious to one having ordinary skill in the art the time of invention. More specifically, it would have been obvious to one having ordinary skill in the art to evaluate the condition of the uterus of a patient in order to decide which type of IUD to place into the uterus. Further, it would have been obvious *prima facie* to one having ordinary skill in the art to insert a presterilized implant in order to prevent the spread of bacteria into the uterus.

As regards claim 2, the purpose of inserting the device into the uterus is to achieve contraception. Accordingly, the device would not be removed until contraception is achieved.

As regards claim 8, Moulding et al. fail to teach that the device is constructed from polyester. However, it has been held that the selection of a material based upon its suitability for the intended use is a design consideration within the level of ordinary skill in the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Thus, absent

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a critical teaching and/or a showing of unexpected results derived from the use of polyester as a material of construction for the implant, the examiner contends that it would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to use polyester or any other material that is suitable.

As regards claim 9, Moulding, Jr. discloses that use of a delivery tool , but fails to teach the delivery too is a catheter. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to insert the implant into uterus with a catheter since they are well known delivery tools for implants for use throughout the entire human body.

As regards claim 10 , the implant discussed above in the rejection of claim 1 is self-contained.

As regards claim 11, the implant discussed above in the rejection of claim 1 may comprise mesh material.

As regards claim 12 and the obviousness of polyester, note the rejection of claim 3 above.

As regards claim 14, the implant can be considered as comprising a frame (note Fig. 6). Also, as stated above the implant may comprise mesh.

As regards claim 15, note the rejection of claim 14 above, and the obviousness discussion of constructing the device from polyester in the rejection of claim 3 above.

As regards claim 16, note fig. 6, which discloses longitudinal extensions extending, which will extend across the uterine wall when the implant is positioned in the uterus.

As regards claim 17, as can be read from the disclosure of the Moulding, Jr. implant is expandable and collapsible (col. 3, line 59- col. 5, line 52).

As regards claim 19, the material (substance) from which the implant is constructed is sized and shaped to cause contraception.

As regards claim 36, note the rejection of claim 1 and 8 above.

As regards claim 38, the purpose of inserting the device into the uterus is to achieve contraception. Accordingly, the device would not be removed until contraception is achieved.

As regards claim 43, Moulding, Jr. discloses that implant is introduced using a catheter. However, the examiner contends that it would have been *prima facie* obvious to one having ordinary skill in the art to insert the implant into uterus with a catheter since they are well known delivery tools for implants for use throughout the entire human body.

As regards claim 44, note the rejections of claims 10 and 11 above.

As regards claim 45, note the rejections of claims 10, 11 and 12 above.

As regards claim 47 note the rejections of claims 14 and 44 above.

As regards claim 48, note the rejections of claims 10, 11 and 12 above.

As regards claim 49, note the rejections of claims 16 and 47 above.

As regards claim 50, note the rejections of claims 17 and 49 above.

As regards claim 52, note the rejections of claims 19 and 44 above.

As regards claim 53, note the rejection of claim 44 above.

As regards claim 54, note the rejection of claim 45 above.

As regards claim 56, note the rejection of claim 47 above.

As regards claim 57, note the rejection of claim 49 above.

As regards claim 58, note the rejection of claim 50 above.

As regards claim 60, note the rejection of claim 52 above.

As regards claim 61, note the rejection of claims 44 and 47 above.

As regards claim 62, note the rejection of claim 48 above.

As regards claim 64, note the rejection of claim 49 above.

As regards claim 65, note the rejection of claim 50 above.

As regards claim 67, note the rejection of claim 52 above.

***Allowable Subject Matter***

4. Claims 20-35 are allowed.
5. Claims 2, 4-7, 13, 18, 37, 39-42, 46, 51, 55, 59, 63 and 66 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

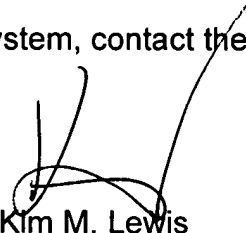
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Monday to Thursday from 5:30 am to 12:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis  
Primary Examiner  
Art Unit 3743

kml  
November 28, 2005